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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,330	12/31/2003	John N. Vournakis	7867-036-999	8226
20583	7590	08/19/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER KIDWELL, MICHELE M	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,330	Applicant(s) VOURNAKIS ET AL.	
	Examiner Michele Kidwell	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,25,27,33-36 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-24,26,28-32,37,38 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/11/05;1/29/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1, 3, 25, 27, 33 – 36 and 39 – 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 9, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4 – 5, 7, 14 – 15, 21 – 22, 26, 28 – 29, 31, 37 – 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipshidze et al. (US 5,437,292).

With respect to claims 2 and 4, Kipshidze et al. (hereinafter “Kipshidze”) discloses a method for treating a puncture in a femoral artery resulting from a cardiac catheterization procedure in a patient, comprising: a) applying topically to the patient's skin over a catheter exit site a composition comprising an effective amount of a epinephrine, wherein the vasoconstrictor does not comprise a poly-.beta.-1 → 4 N-acetylglucosamine polymer or derivative thereof, and wherein the catheter exit site is contiguous with the catheter puncture in the femoral artery by 1-10 cm; and

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concurrently b) applying compression to the punctured vein or artery, wherein a cessation or reduction of blood flow out of the breach or puncture in the femoral artery is achieved in 30%-50% less time than applying compression in conjunction with a topical barrier-forming material without said vasoconstrictor as set forth in col. 3, lines 22 – 65.

Regarding claim 5, Kipshidze discloses a composition further comprising an anti-fungal or antibacterial agent as set forth in col. 8, lines 40 – 44.

As to claim 7, Kipshidze discloses a method further comprising a pharmaceutical carrier as set forth in col. 7, lines 54 – 60.

With reference to claim 14, Kipshidze discloses a method wherein the composition further comprises a coagulant as set forth in col. 7, lines 49 – 60.

With respect to claim 15, Kipshidze discloses a method wherein the patient is a human as set forth in col. 4, lines 4 – 6.

As to claims 21 and 22, Kipshidze discloses a method further comprising before step (a) the step of administering heparin to the patient as set forth in col. 8, lines 50 - 54.

With reference to claim 26, Kipshidze discloses a method wherein the compression is manual compression as set forth in col. 8, lines 53 – 59.

As to claims 28, 29 and 38, Kipshidze discloses a method wherein the compression is applied to the vein or artery proximal of the puncture or breach as set forth in the abstract and figures.

Regarding claim 31, Kipshidze discloses a method further comprising, repeating

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step (b) as set forth in col. 6, lines 11 – 21.

As to claim 37, Kipshidze discloses a method wherein the vein or artery is breached or punctured by a catheter as set forth in col. 4, lines 50 – 53.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 19 – 20, 23 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292) in view of Coury et al. (US 6,162,241).

The difference between Kipshidze and claim 6 is the provision that the composition further comprises collagen.

Coury et al. (hereinafter "Coury") teaches a composition further comprising collagen as set forth in col. 6, lines 49 - 56.

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to include collagen because collagen activates or catalyzes the natural pathways of clotting as taught by Coury in col. 6, lines 49 - 56.

As to claims 19 – 20 and 42, see the rejection of claim 6.

The difference between Kipshidze and claim 23 is the provision that the composition further comprises protamine sulfate.

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Coury teaches a composition further comprising protamine sulfate as set forth in col. 7, lines 28 - 31.

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to include protamine sulfate because the use of such acts as an antidote to anticoagulation as taught by Coury in col. 7, lines 28 – 31.

Claims 8 – 13, 16 – 18, 24 and 30 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292) in view of Cochrum et al. (US 2002/0197302).

The difference between Kipshidze and claim 8 is the provision that the composition is formulated as a solid.

Cochrum et al. (hereinafter "Cochrum") teaches a composition formulated as a solid as set forth in [0205], and specifically a gauze [0218].

It would have been obvious to one of ordinary skill in the art to formulate the composition of Kipshidze as a solid because the use of such rapidly arrests bleeding and promotes rapid clot formation as taught by Cochrum in [0205].

With respect to claims 9 – 13 and 18, see the rejection of claim 8.

As to claim 16, Cochrum discloses a composition applied as a film as set forth in [0224].

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to apply it as a film or membrane because the flim/membrane is thinner and more flexible and therefore will have a decreased foreign body sensation as taught by Cochrum in [0224].

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As to claim 17, see the rejection of claim 16.

With reference to claim 24, Kipshidze discloses the method related to various types of procedures which may relate to the femoral artery as set forth in col. 3, line 61 to col. 4, line 4.

Cochrum teaches a similar concept relating to the femoral artery as set forth in [0235].

It would have been obvious to one of ordinary skill in the art to employ the method of Kipshidze to the femoral artery because the femoral artery is the largest artery which may result in rapid life-threatening blood loss if punctured and not immediately stabilized.

The difference between Kipshidze and claim 30 is the provision that the compression is applied with a compression bandage.

Cochrum et al. (hereinafter "Cochrum") teaches the compression is applied with a compression bandage as set forth in [0072].

It would have been obvious to one of ordinary skill in the art to employ a compression bandage in combination with the composition of Kipshidze because the use of such induces rapid blood coagulation while maintaining constant and direct pressure on the site as taught by Cochrum in [0072].

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292)

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With reference to claim 32, the examiner contends that the method disclosed by Kipshidze is identical to that claimed as set forth in the rejection of claim 2 and would therefore result in the rate as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/
Primary Examiner, Art Unit 3761